Complete Summary

GUIDELINE TITLE

Management of genital Chlamydia trachomatis infection. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network. Management of genital Chlamydia trachomatis infection. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2009 Mar. 42 p. (SIGN publication; no. 109). [160 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline will be considered for review in three years. Any amendments to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Chlamydia trachomatis infection

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

Prevention
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine
Urology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments
Social Workers
Students

GUIDELINE OBJECTIVE(S)

- To present evidence-based recommendations for the prevention, diagnosis, treatment and management of chlamydial infection
- To advise on policy for the most cost-effective testing strategy at a population level and to consolidate best practice in the management of individual cases of diagnosed genital chlamydial infection

TARGET POPULATION

- Individual patients presenting with signs and symptoms of genital chlamydial infection
- Asymptomatic patients in the following specific circumstances:
    - Sexual partners of chlamydia-positive individuals
    - Sexual partners of those with suspected but undiagnosed chlamydial infection
    - Those who have been diagnosed with chlamydia in the previous 12 months
    - All patients attending genitourinary medicine (GUM)Â clinics
    - Those who have had two or more partners in the past 12 months
    - All women undergoing termination of pregnancy
    - All men who have sex with men (MSM) attending GUM clinics
    - Asymptomatic heterosexual patients requesting an sexually transmitted infection (STI) screen
    - Men who have sex with men

- Heterosexual patients whose partners include intravenous drug users, bisexual men, or people who have had unprotected sex in high-risk geographical areas abroad

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Screening

1. Assessment of signs and symptoms
2. Targeted testing of specific groups
3. Nucleic acid amplification assay (NAAT)
4. Dual test (combined with gonorrhoea)
5. Specimen collection (endocervical/vaginal swab, first void urine, self-obtained low vaginal swab)
6. Testing for other sexually transmitted infections

Management/Treatment

1. Azithromycin or doxycycline (for uncomplicated infection)
2. Azithromycin or erythromycin or amoxicillin (for uncomplicated infection in pregnancy)
3. Doxycycline plus metronidazole or ofloxacin plus metronidazole (for chlamydial salpingitis)
4. Doxycycline (for chlamydial epididymo-orchitis or lymphogranuloma venereum)
5. Azithromycin or doxycycline (for rectal infection)
6. Referral to genito-urinary medicine clinic
7. Follow-up and test for cure (as indicated)
8. Partner notification
9. Patient education in primary prevention and re-infection

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic testing
- Morbidity associated with chlamydial infection
- Microbiological cure rate
- Incidence of side effects from treatment
- Re-infection rate
- Transmission rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence base for this guideline was synthesised in accordance with The Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Information Officer. Databases searched include Medline, Embase, Cinahl, and the Cochrane Library. The date range covered by the search to update this guideline was 1999- October 2007. Internet searches were carried out on various websites including the New Zealand Guidelines Programme, NeLH Guidelines Finder, Guidelines International Network, and the US National Guidelines Clearinghouse. Articles relating to *Chlamydia pneumoniae* were excluded. All articles that were not related to the diagnosis or management of genital *Chlamydia trachomatis* infection were excluded. Where sufficient evidence was felt to be available in the English literature, the non-English literature was not reviewed. The main searches were supplemented by material identified by individual members of the guideline development group and peer reviewers. Each of the selected papers was evaluated by two members of the group using standard SIGN methodological checklists before conclusions were considered as evidence.

Literature Search for Patient Issues

A search for studies identifying issues of concern to patients with genital *Chlamydia trachomatis* infection was conducted using the SIGN patient information filter. Databases searched include Medline, Embase, Cinahl, PsycINFO, and the Cochrane Library. The date range covered was 1999-May 2007. The SIGN Patient Involvement Officer analysed the search results to identify themes in the literature. This analysis was used to inform section 8 of the guideline along with original research conducted in one to one interviews in November 2007 with 24 patients at a sexual health clinic in Scotland.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of Randomized Controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g., case reports, case series

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgement. The extent to which a study meets a particular criterion – e.g., an acceptable level of loss to follow up – and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two individuals. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by SIGN Executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the

systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgment is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgment on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgement

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, Scottish Intercollegiate Guidelines Network (SIGN) has introduced the concept of considered judgment.

Under the heading of considered judgment, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence

- External validity (generalisability) of studies
- Directness of application to the target population for the guideline
- Any evidence of potential harms associated with implementation of a recommendation
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources required by National Health Service [NHS] Scotland to treat them in accordance with the recommendation)
- Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made
- Implementability (i.e., how practical it would be for the NHS Scotland to implement the recommendation)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgment. Once they have considered these issues, the group is asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 6 of the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4 *or*

Extrapolated evidence from studies rated as 2+

Note: **Good Practice Points**: Recommended best practice based on the clinical experience of the guideline development group are also included in the original guideline document

COST ANALYSIS

A budget impact report and an associated spreadsheet have been developed to provide each National Health Service (NHS) board with resource and cost information to support the implementation of three recommendations judged to have a material impact on resources (see Table 3 in the original guideline document). These documents are available from the NHS Quality Improvement Scotland (QIS) website: www.nhshealthquality.org.

By reducing the spread of infection and re-infection, implementation of these recommendations will lead to reduced testing and treatment costs in future, as well as patient and clinical benefits. These benefits have not been quantified or costed.

The total costs of implementing these three recommendations across NHS Scotland are estimated to be 533,100 pounds stirling in the first year. The estimated additional resources required across Scotland are 3,900 general practitioner (GP) hours, 1,700 practice nurse hours, 560 health adviser hours, 60 genitourinary medicine (GUM) consultant hours and 1,070 receptionist or staff member hours. The remaining expenditure is mainly on 13,000 laboratory tests and drugs for 7,000 treatments. These figures are based on an assumed staffing ratio of 70% GPs/30% nurses.

These costs would be reduced by 98,000 pounds stirling if a health adviser or a trained practice nurse replaced the GP to give a ratio of 30% GPs/70% nurses.

Some of these costs would overlap with the costs necessary to meet the NHS QIS sexual health standards on partner notification and testing for young people. If both the standards and the guideline are implemented, the additional first year costs of implementing these three recommendations across NHS Scotland would be 333,100 pounds stirling.

For a full description of the assumed parameters and sensitivity analyses, see the budget impact report.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Public Consultation

The draft guideline was available on the Scottish Intercollegiate Guidelines Network (SIGN) website from 30 June to 31 July 2008 to allow all interested parties to comment on the draft guideline.

Specialist Review

This guideline was also reviewed in draft form by independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. The guideline group addresses every comment made by an external reviewer and must justify any disagreement with the reviewers' comments. (See the original guideline document for a list of the reviewers.)

SIGN Editorial Group

As a final quality control check, the guideline is reviewed by an editorial group comprising the relevant specialty representatives on SIGN Council to ensure that the specialist reviewers'Â comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. See the original guideline document for a list of the editorial group for this guideline.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC)*: In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.*

The grades of recommendations (A–D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Key Recommendations

The following recommendations were highlighted by the guideline development group as being clinically very important. They are the key clinical recommendations that should be prioritized for implementation. The clinical importance of these recommendations is not dependent on the strength of the supporting evidence.

Testing

In the absence of data to support a complication rate of 10% or more in women with untreated chlamydial infection, there is no evidence that a screening programme for chlamydia is cost effective with regard to reducing morbidity.

D - If the patient is having a speculum examination either an endocervical or vaginal swab can be used to test for chlamydia.

D - Women not undergoing speculum examination should be offered the choice between self obtained low vaginal swab (SOLVS) or first void urine (FVU).

D - Resources for chlamydia testing in women should be targeted where prevalence is known to be highest, i.e., first those aged 15-19 and then those aged 20-24.

D - Resources for chlamydia testing in men should be targeted where prevalence is knownÂ to be highest, i.e., those aged under 25.

D - All patients attending genitourinary medicine (GUM) clinics should be tested for chlamydia.

B - Postal testing kits should be used to increase chlamydia testing among young men.

Treatment

B - Taking compliance with therapy into account, uncomplicated genital chlamydial infection should be treated with azithromycin 1 g as a single oral dose.

B - Taking compliance, tolerability, and efficacy into account, azithromycin 1 g as a single oral dose is recommended for uncomplicated genital chlamydial infection in pregnancy following discussion of the balance of benefits and risks with the patient.

C - Patients diagnosed with chlamydia must receive a partner notification interview.

B - Patients diagnosed with chlamydia in general practice should be offered a choice of provider for initial partner notification – either trained practice nurses with support from health advisers in GUM, or referral to GUM.

Follow Up

D - All patients treated for chlamydia should be given a follow-up interview within 2-4 weeks of treatment.

D - Test for re-infection should be recommended at 3-12 months, or sooner if there is a change of partner.

C - For prevention of sexually transmitted infection (STIs), including chlamydia, condom use should be promoted in all settings where sexual health care is provided.

Laboratory Tests

Choice of Test

C - Aptima Combo 2 *(TMA)* and BD Probetec *(SDA)* are recommended tests for chlamydial infection.

D - Real time polymerase chain reaction (PCR) can be used as an alternative to transcription mediated amplification (TMA) and strand displacement amplification (SDA).

C - Either single or dual *(combined with gonorrhoea)* tests can be used to test for chlamydial infection.

Choice of Specimen

D - If the patient is having a speculum examination either an endocervical or vaginal swab can be used to test for chlamydia.

D - Women not undergoing speculum examination should be offered the choice between SOLVS or FVU.

D - In men, FVU is the specimen of choice.

Testing for Genital Chlamydial Infection

Patients with Symptoms/Signs of Chlamydial Infection

C - Testing for chlamydia should be performed in women and men with any of the following symptoms and signs:

- Women
    - Vaginal discharge
    - Post-coital/intermenstrual/breakthrough bleeding
    - Inflamed/friable cervix *(which may bleed on contact)*
    - Urethritis
    - Pelvic inflammatory disease (PID)
    - Lower abdominal pain in the sexually active
    - Reactive arthritis in the sexually active
- Men
    - Urethral discharge
    - Dysuria
    - Urethritis
    - Epididymo-orchitis in the sexually active
    - Reactive arthritis in the sexually active

Asymptomatic Groups at Risk of Chlamydial Infection

C - Sexual partners of chlamydia-positive individuals should be tested.

D - Sexual partners of those with suspected but undiagnosed chlamydial infection (with PID or epididymo-orchitis) should be tested.

D - Those who have been diagnosed with chlamydia in the previous 12 months should be tested.

D - All patients attending GUM clinics should be tested for chlamydia.

D - In healthcare settings other than GUM, testing should be most strongly advised for those who have had two or more partners in the past 12 months.

D - Resources for chlamydia testing in women should be targeted where prevalence is known to be highest, i.e., first those aged 15-19 and then those aged 20-24.Â

A - All women undergoing termination of pregnancy should be tested for chlamydial infection.

D - Resources for chlamydia testing in men should be targeted where prevalence is known to be highest, i.e., those aged under 25.

B - Postal testing kits should be used to increase chlamydia testing among young men.

D - All men who have sex with men (MSM) attending GUM clinics, including those who are HIV-positive, should be offered chlamydia testing, including rectal swabs.

Testing for Other Sexually Transmitted Infections

D - Asymptomatic heterosexual patients requesting an STI screen can be offered a chlamydia test alone in the absence of other risk factors.

D - MSM should be offered a full sexual health screen, including human immunodeficiency virus (HIV), syphilis, gonorrhoea, and rectal chlamydia testing, depending on their individual risk.

D - Heterosexual patients whose partners include intravenous drug users, bisexual men, or people who have had unprotected sex in high-risk geographical areas abroad should be offered tests for other STIs, depending on their individual risk.

Antimicrobial Treatment

Initiation of Treatment

C - Initiate treatment without waiting for laboratory confirmation of infection in patients with symptoms and signs of chlamydial infection and their sexual partners.

Uncomplicated Infection

A - Uncomplicated genital chlamydial infection may be treated with either azithromycin 1 g as a single oral dose or doxycycline 100 mg twice daily for seven days.

B - Taking compliance with therapy into account, uncomplicated genital chlamydial infection should be treated with azithromycin 1 g as a single oral dose.

Uncomplicated Infection in Pregnancy

A - Uncomplicated genital chlamydial infection in pregnancy should be treated with

- Azithromycin 1 g as a single oral dose

  or

- Erythromycin 500 mg four times daily orally for seven days

  or

- Amoxicillin 500 mg three times daily orally for seven days

B - Taking compliance, tolerability, and efficacy into account, azithromycin 1 g as a single oral dose is recommended for uncomplicated genital chlamydial infection in pregnancy following discussion of the balance of benefits and risks with the patient.

Chlamydial Salpingitis

D - Chlamydial salpingitis should be treated with doxycycline 100 mg twice daily for 14 days plus metronidazole 400 mg twice daily for 14 days.

D - Ofloxacin 400 mg twice daily for 14 days may be used as an alternative to doxycycline.

Chlamydial Epididymo-orchitis

D - The recommended treatment for chlamydial epididymo-orchitis in men is doxycycline 100 mg twice daily for 10-14 days.

Rectal Infections in Men

D - Rectal infection may be treated with either azithromycin 1 g as a single oral dose or doxycycline 100 mg twice daily for seven days.

D - If lymphogranuloma venereum (LGV) is diagnosed, or suspected on clinical grounds, the recommended regimen is doxycycline 100 mg twice daily for three weeks.

Follow Up and Test of Cure

D - All patients treated for chlamydia should be given a follow-up interview within 2-4 weeks of treatment.

D - Telephone follow up may be used as an alternative to face-to face interviews.

D - Adherence with therapy and risk of re-infection should be discussed with patients at follow-up interviews.

D - A test of cure need not be performed in patients who have adhered to therapy and in whom there is no risk of re-infection.

D - Test of cure should be routine during pregnancy.

D - Test of cure/re-infection established by nucleic acid amplification test (NAAT) should be performed a minimum of five weeks after the initiation of therapy *(six weeks after azithromycin)*, to avoid false positive results.

Long Term Follow–up

D - Test for re-infection should be recommended at 3-12 months, or sooner if there is a change of partner.

Partner Notification

C - Patients diagnosed with chlamydia must receive a partner notification interview.

Methods of Partner Notification

B - Patients should be given a choice of patient or provider referral.

B - Patients diagnosed with chlamydia in general practice should be offered a choice of provider for initial partner notification – either trained practice nurses with support from health advisers in GUM, or referral to GUM.

Additional Interventions for Partners

C - Patients with chlamydia should be offered additional written information for partners, with accompanying guidance for healthcare professionals.

Time Period for Identifying Previous Partners

D - In men with symptomatic chlamydial infection, all partners from the four weeks prior to onset of symptoms should be contacted.

D - In women and asymptomatic men, all partners from the last six months or the most recent sexual partner *(if outwith that time period)* should be contacted.

Health Education in Primary Prevention and Prevention of Re-infection

Primary Prevention

B - Client centered, risk reduction focused, one to one counselling involving behavioural goal setting should be considered during consultations for sexual and reproductive health issues.

C - For prevention of STIs, including chlamydia, condom use should be promoted in all settings where sexual health care is provided.

General Public

C - Opportunities should be taken to deliver education in a wide variety of non-healthcare settings, e.g., youth clubs, community centres, and schools. Education about chlamydial infection should be integrated with other sexual health education and condomÂ promotion initiatives.

D - Social marketing campaigns targeted toward those at risk should continue to raise awareness of chlamydial infection.

Definitions:

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of Randomized Controlled trials (RCTs), or RCTs with a very low risk of bias

1+W: Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g., case reports, case series

4: Expert opinion

Grades of Recommendations

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1^{++} and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4 *or*

Extrapolated evidence from studies rated as 2+

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of genital *Chlamydia trachomatis* infection

POTENTIAL HARMS

- Side effects of therapy
- Psychological distress from diagnosis
- Discomfort from some methods of testing

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Every care is taken to ensure that this publication is correct in every detail at the time of publication. However, in the event of errors or omissions corrections will be published in the web version of this document, which is the definitive version at all times. This version can be found on the Scottish Intercollegiate Guidelines Network (SIGN) web site www.sign.ac.uk.

This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is advised, however, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

Prescribing of medicines without their marketing authorisation: Recommendations within this guideline are based on the best clinical evidence. Some recommendations may be for medicines prescribed outwith the marketing authorisation (product licence). This is known as "off label" use. It is not unusual for medicines to be prescribed outwith their product licence and this can be necessary for a variety of reasons. Generally the unlicensed use of medicines becomes necessary if the clinical need cannot be met by licensed medicines; such use should be supported by appropriate evidence and experience.Â

Medicines may be prescribed without their product licence in the following circumstances:

- For an indication not specified within the marketing authorization
- For administration via a different route
- For administration of a different dose

Prescribing medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescribers' professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

Any practitioner following a Scottish Intercollegiate Guidelines Network (SIGN) recommendation and prescribing a licensed medicine without the product licence needs to be aware that they are responsible for this decision, and in the event of adverse outcomes, may be required to justify the actions that they have taken.

Prior to prescribing, the licensing status of a medication should be checked in the current version of the British National Formulary (BNF).Â

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Board and is an essential part of clinical governance. Mechanisms should be in place to review care provided against the guideline

recommendations. The reasons for any differences should be assessed and addressed where appropriate. Local arrangements should then be made to implement the national guideline in individual hospitals, units and practices. The guideline development group has identified the key points to audit to assist with the implementation of this guideline.

Resource implications of key recommendations are available in section 9.1 of the original guideline document.

Auditing Current Practice

National Targets

NHS QIS has established standards for sexual health services that include audit criteria. The standards are available from the NHS QIS website: www.nhshealthquality.org.

The guideline development group has identified the following as key points to audit to assist with the implementation of this guideline:

Regional Targets

- Number of tests per head of population
- Number of tests carried out in men
- Development and dissemination of information materials to health professionals and the general public

Targets Within Departments, Clinics, Health Centres, Etc.

General

- Rates of referral to genitourinary medicine (GUM) health advisers from other settings

Diagnostic Testing

- Percentage of women with suspected pelvic inflammatory disease (PID) tested for chlamydial infection
- Percentage of men with epididymitis tested for chlamydial infection

Testing Specific Asymptomatic Groups

- Percentage of chlamydia tests per year taken from males aged under 25
- Percentage of chlamydia tests per year taken from females aged 15-19
- Percentage of chlamydia tests per year taken from females aged 20-24
- Percentage of women tested before termination of pregnancy (TOP)
- Percentage of patients attendingÂ GUM clinics offered chlamydia testing
- Percentage of men who have sex with men (MSM) attending GUM clinics offered chlamydia testing

Follow-up Rate

- Partner notification success rates
- Percentage of patients with chlamydial infection who receive a follow-up interview within four weeks
- Percentage of patients with chlamydia who are retested 3-12 months later

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Quick Reference Guides/Physician Guides
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Mar (revised 2009 Mar)

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Dr Gordon Scott (*Chair*), Consultant in Genitourinary Medicine, Royal Infirmary of Edinburgh; Dr Sharmini Ramasami (Secretary), Specialist Registrar in Genitourinary Medicine, Royal Infirmary of Edinburgh; Dr Steve Baguley, Consultant, Genitourinary Physician, Woolmanhill Hospital, Aberdeen; Dr Audrey Brown, Consultant in Family Planning and Reproductive Health, The Sandyford Initiative, Glasgow; Dr Emilia Crighton, Consultant in Public Health Medicine, NHS Greater Glasgow and Clyde; Dr Alison Currie, Consultant in Genitourinary Medicine, Monklands Hospital, Airdrie; Ms Jenny Dalrymple, Sexual Health Adviser, The Sandyford Initiative, Glasgow; Dr Elizabeth Daniels, General Practitioner, Keith Health Centre, Moray; Dr Jayshree Dave, Consultant Microbiologist and Director, Scottish Bacterial Sexually Transmitted Infections Reference Laboratory (SBSTIRL), Edinburgh; Ms Ysobel Gourlay, Senior Pharmacist HIV/ID Antimicrobial Utilisation, Gartnavel General Hospital, Glasgow; Dr Maggie Gurney, Associate Specialist, Department of Sexual Health and Director of Sexual Health, Dumfries and Galloway; Ms Michele Hilton Boon, Programme Manager, SIGN; Ms Joanna Kelly, Information Officer, SIGN; Ms Shelagh Mason, Practice Nurse, Primrose Lane Medical Centre, Rosyth; Dr Michelle McIntyre, General Practitioner, University Health Centre, Edinburgh; Miss Margaret Totten, Lay Representative, Paisley; Dr Rennie Urquhart, Consultant Gynaecologist, Forth Park Hospital, Kirkcaldy; Dr Lisa Williamson, Research Scientist, MRC Social and Public Health Sciences Unit, Glasgow

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the guideline development group made declarations of interest and further details of these are available on request from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline will be considered for review in three years. Any amendments to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Management of genital *Chlamydia trachomatis* infection. Scottish Intercollegiate Guidelines Network, 2009 Mar. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- Management of genital *Chlamydia trachomatis* infection. Recommendations online: clinical knowledge evidence translation (ROCKET). Scottish Intercollegiate Guidelines Network, 2009 Mar. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the SIGN Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Electronic copies: Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Electronic copies: Available from SIGN Web site.
- Management of genital *Chlamydia trachomatis* infection. A resource and budget report.Â Scottish Intercollegiate Guidelines Network, 2009 Mar. 24 p.Â Electronic copies: AvailableÂ in Portable Document Format (PDF) from the SIGN Web site.
- Management of genital *Chlamydia trachomatis* infection costing tools. Scottish Intercollegiate Guidelines Network, 2009 Mar.Â Electronic copies: AvailableÂ from the SIGN Web site.

Additionally, suggested audit targets can be found in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 11, 2000. The information was verified by the guideline developer on October 17, 2000. This guideline was updatedÂ by ECRI Institute on November 4, 2009.

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